



B&R Compliance Associates LLC
Regulatory Update Bulletin

**Bulletin
Number**
BR08-001

1/16/08

**FDA Annual Registration & Drug Product Listing
Requirements**

Page 1 of 1

IMPORTANT: Annual Registration & Drug Product Listing forms are no longer automatically sent to your facility. It is your responsibility to obtain the appropriate forms and update as required.

Registration Overview – Drugs

Manufacturers of medical drug gases must register and list with the FDA within 5 days of beginning operations. Registration is accomplished by completing form FDA 2656, "Registration of Drug Establishment/Labeler Code Assignment". Subsequent annual registration is required on form FDA 2656. If you want to check your current Registration to see what your current status is you can go the site below: www.fda.gov/cder/dfars/default.htm

Listing Overview – Drugs

When you register initially, you must also submit a drug product listing (DPL) on form FDA 2657. The purpose of this form is to inform the FDA of drug gases you manufacture, their package sizes and quantities, and to submit sample labeling.

Subsequent review and update of DPL's are required in June and December of each year. These are to be used whenever products or package sizes are added or discontinued or labeling has changed. If you have had no changes from the prior listing, you are not required to update.

Copies of your current registration, listing and labeling must be made available for FDA inspection. If you want to check your current Drug Product Listing to see what your current status is so that you know if you need to make any changes, you can go the site below, and then choose firm name, product proprietary name (oxygen, etc.) or by labeler code which can be found on your annual registration. www.fda.gov/cder/ndc/database

Resource Links

FDA 2656 Form: <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2656.pdf>

FDA 2657 Form: <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2657.pdf>

FDA 2656 & 2657 Instructions: <http://www.fda.gov/cder/drls/default.htm>

Note: Do not send Fed Ex or other courier packages containing your 2656 or 2657 forms to the courier address currently listed in the Drug Registration Packet and currently on the FDA Website. Use the following address:

5901B Ammendale Road (HFD-143)
Beltsville, MD 20705

**For more information on this subject, or any other medical
gases compliance issue please contact Ron Ball at
(317) 297-8518, or ron.ball@brcompliance.com.**